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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,744	08/20/2003	Steve T. Lin	19870.052201	9151

32361 7590 02/23/2009

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
02/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/645,744	LIN ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-28 and 30-111* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,13,16,18,19,24,27,28,30-37,39,43,45,46,51 and 104-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/09/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12,14,15,17,20-23,25,26,38,40-42,44,47-50,52-103 and 108-111.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks and IDS, all filed 12/09/08. Claims 1, 2, 4, 27, 28, 30 and 104-107 are amended. Claims 3 and 29 are canceled. Claims 1, 2, 4-28 and 30-111 are pending.

On the basis of the demineralized bone matrix, claims 4 and 30 were withdrawn from consideration, but the current amendment to claims 4 and 30 reciting demineralized bone matrix necessitates inclusion of claims 4 and 30 in the examined claims.

Previous rejections that re not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, 4, 4-11, 13, 16, 18, 19, 24, 27, 28, 30-37, 39, 43, 45, 46, 51 and 104-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Currently amended claims 1, 27, 104 and 106 recite the "weight of the demineralized bone matrix ranges from about 20% to about 40% of the composition by weight." Applicant

says that page 29, lines 1-9 provides support for the demineralized bone matrix that ranges from about 20% to about 40%. However, page 29, lines 6 and 7 provide support for specific individual concentrations of 20, 30 and 40%. A range of about 20% to 40% represents a continuum of points within the range and the specific concentration points of 20, 30 and 40% do not represent other points between 20 and 30 and 30 and 40%. Therefore, the concentration range of demineralized bone matrix of from about 20% to about 40% is not envisioned at the time of the original invention. Applicant may overcome the new matter rejection by removing the new matter from the claims.

Response to Arguments

3. Applicant's arguments filed 12/09/08 have been fully considered but they are not persuasive. Applicant feels that the amendment is supported by page 29, lines 1-9, but as described above, page 29, lines 1-9 do not provide the recited range of about 20% to about 40%.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 5-11, 13, 16, 18, 19, 24, 27, 28, 31-37, 39, 43, 45, 46, 51 and 104-107 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jarrett et al. (WO 98/12243) in view of Helm et al. ("Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous bone lumber spinal fusion," in J Neurosurg 86: 93-100, 1997) or Bolander et al. ("The use of Demineralized Bone Matrix in the Repair of Segmental Defects," in the Journal of Bone and Joint Surgery, 1986, 1264-1274) for reasons of record and reiterated herein.

Jarret teaches macromer carrier composition (abstract), the macromers are block copolymers including water soluble block, at least one biodegradable block and at least one polymerizable group (page 2, line 28 to page 3 line 1); at least one of the biodegradable block comprises carbonate or dioxanone and the macromer can also contain other degradable linkages or groups in addition to the carbonate or dioxanone (page 3, lines 1-4) with poly(hydroxyl acid) such as lactic acid and glycolic acid, polycaprolactones, polyorthoesters, polyanhydrides (page 3, lines 9-13; page 15, lines 4-23) as the other degradable linkages; such other linkage; the carbonate may come from trimethylene carbonate (Figures 1 and 3; page 15, lines 25-28); the structure of the macromer meets the structure of the claimed macromer in claims 1, 24, 27, 51, 104 and 106. The carrier composition is used as a drug delivery device for the delivery of therapeutic agents (page 1, lines 4 and 5; page 27, line 2 to page 28 line 13), used in sealing leaks

in tissue (page 24, lines 9-29) and in orthopedic surgery, it can be used as bone repair (page 25, lines 11 and 12). The carrier composition may also contain free radical photoinitiator such as eosin or eosin Y (page 26, lines 28-31) meeting claims 10, 11, 13, 36, 37 and 39. The carrier composition is aqueous (page 26, line 25) meeting claims 2, 28, 105 and 107. The carrier composition is applicable for human use (page 14, line 18; page 33, line 27) meeting the claims requiring vertebrates and humans, claims 5, 8, 9, 34 and 35. The presence of hyaluronic acid, dextran and heparin (page 14, lines 9-11) meets the limitation of additive in claims 18 and 19. See also page 9, line 22 to page 17, line 30. Regarding, the amount of demineralized bone matrix, a person of ordinary skill in the art would have good reason to use appropriate amount of demineralized bone matrix that would be effective for bone repair.

While Jarret discloses the carrier composition of the claimed invention, and while Jarret discloses that the carrier composition is a drug delivery device and specifically mentions the use of the composition for repair of bone, the carrier composition of Jarret does not contain demineralized bone matrix material. However, it is known in the art that demineralized bone matrix is used for bone repair according to Helm and Bolander. Therefore, taking the general teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that inclusion of demineralized bone matrix in the composition of Jarret would effectively repair bone.

Response to Arguments

7. Applicant's arguments filed 2/07/08 have been fully considered but they are not persuasive.

8. Applicant argues that the examiner has used impermissible hindsight in constructing "a hypothetical combination utilizing demineralized bone matrix" because applicant says that other materials besides demineralized bone matrix have been also used for bone repair as shown by exhibits A to D; that the bone repair of Jarret appears to be related to sealing leaks in tissue and that Jarret locally applies prophylactic, therapeutic or diagnostic agent that according to US patent 7,022,343 is used in relatively low level such that the level of active agent would likely be under 10%; applicant further argues that the resorption of the composition and the replacement by new bone as recited by claims 5-7 and 31-33 further distinguish the claims over Jarret.

9. The examiner disagrees with the applicant. Applicant appears to imply that Jarret is only concerned with sealing tissues, but as disclosed on page 25, lines 11 and 12, Jarret also contemplates using the composition to repair bone in orthopedic surgery such that the difference between the claims and Jarret is the absence of bone demineralized bone matrix in the composition. Thus, since Bolander and Helm teach that demineralized bone matrix is used for bone repair, another composition comprising the composition of Jarret and the demineralized bone matrix of Bolander or Helm would successfully provide the anticipated bone repair. While it is true that other agents according to the applicant and supported by the documents in exhibits A-D can be used to repair bone, it is also true that demineralized bone matrix is used to repair bone. Thus inclusion of demineralized bone matrix or any of the other bone repair agents presented by applicant in the argument would also provide the anticipated bone repair in orthopedic surgery. There is therefore no hindsight reconstruction, and it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of

ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, it is within the level of the ordinary skilled artisan to use demineralized bone matrix to repair bone. Furthermore, with respect to applicant's argument that Jarret locally applies prophylactic, therapeutic or diagnostic agent, which according to applicant may be used at less than 10%, it is noted that the comprising language of the claims is open and does not exclude the presence of any prophylactic, therapeutic or diagnostic agent. With respect to claim 5-7 and 31-33, the resorption of the composition is a characteristic of the composition and the composition of Jarret as modified by the addition of demineralized bone matrix of Helm or Bolander would intrinsically have the characteristic of being resorbed or would be capable of being resorbed.

10. Claims 1, 2, 4-11, 13, 16, 18, 19, 24, 27, 28, 30-37, 39, 43, 45, 46, 51 and 104-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarrett et al. (WO 98/12243) in view of Helm et al. ("Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous bone lumber spinal fusion," in J Neurosurg 86: 93-100, 1997) or Bolander et al. ("The use of Demineralized Bone Matrix in the Repair of Segmental Defects," in the Journal of Bone and Joint Surgery, 1986, 1264-1274) and further in view of Maddox et al. ("Optimizing Human Demineralized Bone Matrix for Clinical Application," in Tissue Engineering, Vol. 6, No. 4, 2000, pages 441-448.

11. Claims 1, 2, 5-11, 13, 16, 18, 19, 24, 27, 28, 31-37, 39, 43, 45, 46, 51 and 104-107 have been described above to be rendered obvious by Jarrett et al. (WO 98/12243) in view of Helm et al. ("Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic

protein-2 to enhance autologous bone lumber spinal fusion," in J Neurosurg 86: 93-100, 1997) or Bolander et al. ("The use of Demineralized Bone Matrix in the Repair of Segmental Defects," in the Journal of Bone and Joint Surgery, 1986, 1264-1274).

12. Claims 4 and 30, which by the present amendment recites demineralized bone matrix to be selected from osteoinductor and osteoconductor are now included with the previously examined claims. The combined teaching of Jarret in view of Helm or Bolander is silent on whether the demineralized bone matrix has the characteristic of osteoinduction or osteoconduction as indicated by amended claims 4 and 30. But, these forms of the demineralized bone matrix are innate properties of the demineralized bone matrix as evidenced by Maddox (see abstract; page 446, line 2; page 447, line 8). Therefore, one having ordinary skill in the art at the time the invention was made would reasonable expect that the demineralized bone matrix that is incorporated into the composition of Jarret would have the innate characteristic of osteoconduction or osteoinduction for conducting or inducting ingrowth of natural bone when placed against adjacent natural bone.

No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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